EAR, NOSE AND THROAT DEVICES PANEL

AUGUST 16, 2002

FDA GENERAL ISSUES DISCUSSION TOPIC

The agenda for the August 16, 2002 open session of the Ear, Nose and Throat Devices Panel Meeting is to discuss the enclosed document, "Implantable Middle Ear Hearing Device; Draft Guidance For Industry and FDA." At the June, 1999 Panel Meeting, the Panel discussed many of the issues that were incorporated into the document; however, at this time we are presenting the draft for further comment and recommendation.

While we will ask the Panel to provide their comments on any part of the document, we intend to focus our questions on three particular areas:

a. the role of animal studies in determining safety and effectiveness for the implantable middle ear hearing device (IMEHD);

b. additional assessments, if any, related to the clinical protocol for evaluating the IMEHD; and,

c. the common performance characteristics, e.g., output, gain, frequency response, of the IMEHD.

We have requested that Drs. Paul Kileny, Sigfrid Soli, and Donald Eddington to summarize their responses to the enclosed questions 1, 2a , and 3 respectively. In addition, we have asked them to lead the discussion on those questions and reach consensus on the issues.

PLEASE NOTE: The IMEHD draft guidance is also out for public comment on the FDA website for a period ending September 12, 2002.

http://www.fda.gov/cdrh/ode/guidance/1406.pdf